

Amendments to the Drawing

Replacement Drawing Sheet 2 containing Figure 2 is attached to this Response as Exhibit A. Responsive to the Examiner's objection, Figure 2 has been amended to include appropriate labels. Accordingly, Applicant respectfully requests that this objection be withdrawn.

Remarks/ArgumentsAmendments to the Claims

Claim 1 has been amended to recite "a time limited to less than about... ~~0.12~~ 0.16 seconds...". Support for this amendment is found in Example 3, page 24, line 8 through page 28, line 5.

Double Patenting

Applicant submits a terminal disclaimer over U.S. Patent No. 6,664,114 B1 in order to overcome the obviousness-type double patenting rejection levied by the Examiner.

Rejections under 35 U.S.C. §112

Claims 1-7 and 9-14 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors were in possession of the claimed invention at the time the application was filed. Applicant traverses this rejection and requests its withdrawal for the following reasons.

First, as a preliminary matter, the Examiner points out that using a flow rate of 750 $\mu\text{L}/\text{min}$ (as disclosed, for example, in Example 3, page 24, line 8 – page 28, line 5) and a volume of 2 μL (as disclosed, for example, on page 7, lines 2-4) will give a contact time of 0.16 seconds instead of the claimed 0.12 seconds using the formula: **Contact Time = Volume / Flow Rate**. Applicant agrees with the Examiner's calculation and has amended claim 1 to recite "a time limited to less than about... ~~0.12~~ 0.16 seconds..." Although Applicant submits that the previously recited contact time of 0.12 seconds was in fact disclosed in the application as originally filed (see page 7, line 10 disclosing a flow rate of 1000 $\mu\text{L}/\text{min}$ and page 7, lines 2-4 disclosing a 2 μL volume of analyte: **0.12 seconds = 1000 $\mu\text{L}/\text{min}$ / 2 μL**), Applicant has amended claim 1 solely in order to put the pending claims in condition for allowance.

The Examiner also asserts that the recited contact times were not disclosed in the application as originally filed. Applicant disagrees, for substantially the same reasons given in

the response to the previous Office Action submitted on March 11, 2005. As noted above, contact times can be calculated by using the simple formula: $\text{Contact Time} = \text{Volume} / \text{Flow Rate}$. Using disclosed flow rates of 250 $\mu\text{L}/\text{min}$, 750 $\mu\text{L}/\text{min}$ and 1500 $\mu\text{L}/\text{min}$ (see Example 3) and a disclosed interstitial volume of 2 μL (see page 7, lines 2-4), contact times of 0.48 seconds, 0.16 seconds and 0.08 seconds are obtained. Using this simple formula, one skilled in the art can easily calculate the recited contact times based on the disclosed flow rates and interstitial volumes. Therefore, Applicant submits that these contact times were in fact disclosed in the application as originally filed.

Applicant further responds to the Examiner's comment that "the specification at page 24, example 3, teaches that when the flow rate and the primary antibody concentration and analyte dilution factor are varied, the other two factors must be held constant in order to study the factor that may affect sensitivity and precision using the method as disclosed" by noting that, in fact, the primary antibody concentration and analyte dilution factor are irrelevant for the purposes of calculating a given contact time. That is, varying the primary antibody concentration and analyte dilution factor do not affect the time a given volume of solution (containing the analyte/primary antibody complex) is in contact with the solid phase material (to which is bound a given quantity of analyte). Of the three factors tested in Example 3, only the flow rate of the solution containing the analyte/primary antibody complex has an effect on the contact time.

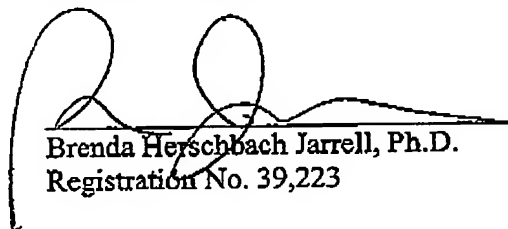
Finally, the Examiner asserts that the contact times recited in the currently pending claims are specific for the flow rates and volumes recited in the specification and are not disclosed as generic for any flow rate and any contact time. Applicant strongly disagrees with this assertion since one of ordinary skill in the art would understand, based on the present disclosure, that limited contact times are extremely useful in achieving significant advantages over traditional competition and sandwich assays. One skilled in the art would therefore understand that the inventors were clearly in possession of limited contact times other than those that can be calculated from the disclosed exemplary flow rates and volumes. However, Applicant points out that the claims currently pending in this application do not recite generic contact times, but instead recite specific contact times of less than about 1 second, 0.48 seconds, 0.16 seconds, and 0.08 seconds. As such, the Examiner's assertion regarding generic contact times is irrelevant to the currently pending claims.

Thus, Applicant respectfully requests that the rejection under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement be removed.

In light of these Remarks and Amendments, Applicant respectfully submits that the present case is in condition for allowance. A Notice to that effect is respectfully requested.

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Respectfully Submitted,



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